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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,500	09/29/2006	Jong Soo Woo	Q97453	9881

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
05/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,500	WOO ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed February 19, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claim 1 has been amended.

2. Claim 1-4 are pending in the case.

3. Claims 1-4 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

6. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

7. Claim 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shell et al. (U.S. Pat. No. 6340475) in view of Chu et al. (U.S. Pat. Pub. 2005/0042289).

Shell et al. teaches a drug controlled release formulation comprising drugs in polymeric matrices that are water-swellable. Specifics are exemplified with metformin hydrochloride. A water-swellable polymer particularly preferred is poly(ethylene oxide). Preferred polyethylene oxides have an average molecular weight of about 100,000 (1 x 10^5) to about 10,000,000 (1x 10^7). Xanthan gum is also preferred can be also used in the formulation.

Shell teaches that the water-swellable polymers can be used individually or in combination. Shell also teaches that certain combinations will provide greater controlled release of the drug than when used individually citing the specific combination of polyethylene oxide and xanthan gum.

The ratio of drug to polymer range is in general from 0.01:99.99 to about 80:20, and the specific examples have ratios of 250:138.67 (equals 1:0.56-Example 1) and 64:35 (equals 1:0.56-Example 5) which are within the limitations of the claims. Other pharmaceutical additives such as magnesium stearate are also taught in the formulation (Abstract, Col. 5, lines 57-63, Col. 6, lines 38-42, Col. 8, lines 29-55, col. 9, lines 40-60, Col. 12, Example 1, Col. 13-14, Example 4-5, Claims 1, 3-4, 9).

Shell et al. does not expressly teach a specific example with metformin hydrochloride with xanthan gum and polyethylene oxide combined, or the ratio of the polyethylene oxide and gum (e.g. xanthan). Shell does however, as addressed above teach the general ratio of drug to polymer range of 0.01:99.99 to about 80:20 with specific metformin examples with POLYOX having ratios of 250:138.67 (equals 1:0.56-Example 1) and 64:35 (equals 1:0.56-Example 5) which are within the limitations of the claims. Shell also teaches the combination of polyethylene oxide and xanthan gum as a desirable combination.

Chu et al. teaches a formulation ratio for sustained (controlled) release with polyethylene oxide and polysaccharides. The polyethylene oxide preferably has a molecular weight of at least about $4x10^6$ Daltons. The polysaccharides include locust bean gum, xanthan gum, and guar gum. The preferred polysaccharide is xanthan gum

and the most preferred ratio of the polyethylene oxide to polysaccharide is between 4:3 to 3:4 (equals 1.33:1 to 0.75:1). Chu teaches that the formulation can be used for any drug including hydrophilic drugs (Abstract, paragraph 5-8, 10, 32-33, claim 1, 3, 8-9, 13-14, 18)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate the combination of metformin hydrochloride, xanthan gum, and polyethylene oxide in the ratios, suggested by Shell et al. and Chu et al., and produce the instant invention. It would have been obvious to one of skill in the art to substitute the POLYOX for the combination of POLYOX and xanthan gum as Shell has taught that the specific combination of polyethylene oxide and xanthan gum would be desirable as that combination would provide a greater controlled release of the drug than when each polymer component was used individually. When a combination of the polyethylene oxide and xanthan gum is used in the ratios exemplified, the ratios addressed above would continue to fulfill the limitations of the claims. It also would have been obvious to one of skill in the art to use Chu's formulation ratio for the PEO and xanthan (polysaccharide) which is taught to improve and optimize the controlled release of the hydrophilic drugs (e.g. metformin) as both Shell and Chu are directed to the controlled release formulations for hydrophilic drugs with the same components (e.g. PEO, xanthan gum) for the same purpose.

One of ordinary skill in the art would have been motivated to do this because a formulation that has a stable sustained release of a hydrophilic drug like metformin and its salts, prevents dose-dumping (sudden release of the drug), which is very desirable

for sustained bioavailability of metformin, especially in a diabetic (primary population of metformin) where stable resulting blood levels is critical.

It is noted that the release recitation is directed to intended use which does not have patentable weight in a composition claim and would be a direct result of the components present in the composition and the ranges which are presented in the claims. When the composition limitations are met, the recitations are also met.

Response to Arguments

8. The 112 2nd rejections are moot in light of the amendments.

9. Applicant's arguments filed 2/19/2009 are moot in light of the amendments and the new grounds of rejection. It is noted however that the comparatives referred to in the arguments (e.g. previous declaration) are not commensurate in scope with the claims as the claims do not include the components present in the comparative or declaration or the composition design (e.g. PVP, PVA, wax) which can influence the t_{90}% values. Additionally the profiles are to the future intended use which does not have patentable weight in composition claims.

Conclusion

10. Claims 1-4 are rejected.

11. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612